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Steven K. Galson, MD Acting Director Center for Drug Evaluation and Research

Dear Dr. Galson,

I strongly urge you to accept the application by Barr Laboratories to make Plan B® emergency contraception available over-the-counter.

I am a practicing gynecologist caring primarily for adolescent and young women at the University of Chicago and have worked in the community setting caring for a similar, although very economically disadvantaged, population. In both settings, I have worked tirelessly to educate women about responsible sexuality and provide them with resources to prevent unintended pregnancy. In my research, clinical and advocacy roles, I have devoted my career to a better understanding of sexual behavior and interventions to prevent unplanned pregnancy and unnecessary abortion. Emergency contraception provides a critical safety-net for advantaged and disadvantaged women — human beings alike who sometimes, for a wide variety of reasons, find themselves faced with the possibility of an unintended pregnancy.

Increasing the availability of emergency contraception could reduce the rate of unintended pregnancies. Currently, half of all pregnancies in the United States (about 3 million) are unintended, and half of these pregnancies end in abortion. Widespread availability of emergency contraception could prevent over one million of these unplanned pregnancies a year.

Emergency contraception is a safe and easy-to-use contraceptive that contains the same hormones commonly found in most birth control pills. It prevents pregnancy prior to fertilization, primarily by inhibiting ovulation, and secondarily by impairing the migration and function of sperm. It is most effective when used within twenty-four hours of unprotected intercourse, although it has been shown to prevent pregnancy for up to three days.

In December 2003, the Reproductive Health Advisory subcommittee recommended approval of emergency contraception for over-the-counter use. Studies conducted by Barr Laboratories, manufacturer of Plan B® emergency contraception, found that women do not substitute emergency contraception for other forms of birth control, they understand the drug labeling, and are not less likely to obtain other health services.

Thank you for your continued support of women's reproductive health. I urge you to approve over-the-counter access to emergency contraception.

Sincerely yours,

Stacy Tessler Lindau, MD, MAPP, FACOG

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